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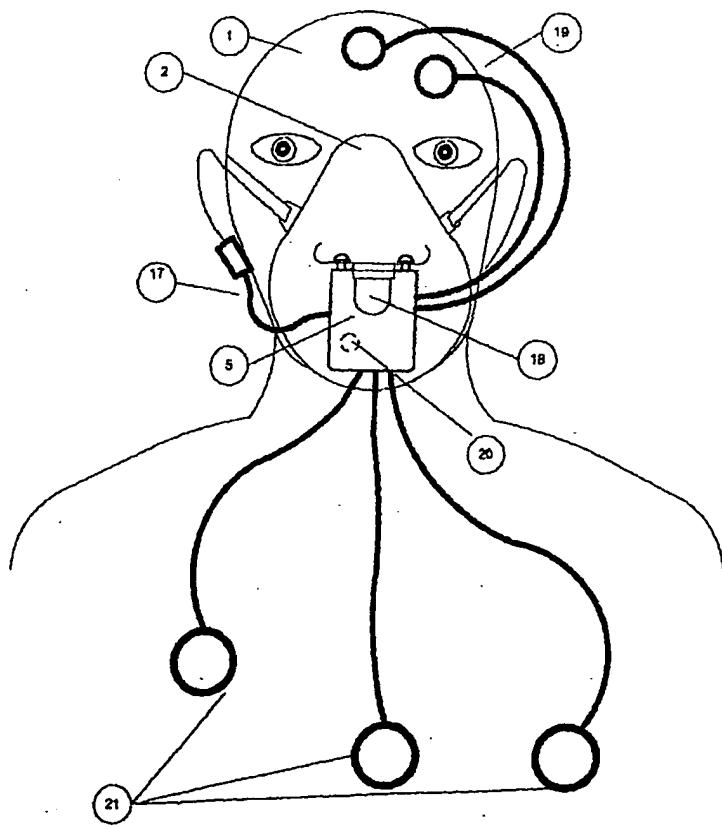
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(54) Title: SYSTEM FOR PHYSIOLOGICAL MONITORING DURING SLEEP



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(57) Abstract: A diagnostic medical device which monitors physiological parameters during sleep is disclosed. The device includes mask means (2) adapted to fit over the nose and mouth of a patient being monitored, and an acquisition unit (5) is adapted to be removably fitted to the mask means (2). The mask means (2) has inlet means (3) to allow the patient to breath, and the acquisition unit (5) includes sensor means (8) which monitor physiological conditions and which provide physiological signals thereto for storage or real time data transmission to external devices.



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SYSTEM FOR PHYSIOLOGICAL MONITORING DURING SLEEP

The present invention relates generally to diagnostic medical devices and, in particular, to a diagnostic medical device which monitors physiological parameters during sleep.

BACKGROUND TO THE INVENTION

Portable diagnostic medical devices are used for monitoring of biological signals of patients in order to detect disease. These devices are used both in the hospital environment and ambulatory settings.

Modern medical diagnostic devices are intelligent data loggers capable of acquiring, analysing and storing biological data into memory. Biological data can be acquired from a single sensor or from a multiplicity of sensors connected to the patient.

Usually sensors such as ECG electrodes, pulse oximetry emitter-detector couple, plethysmography electrodes, EEG electrodes, leg and chest movement sensors, body position sensors, etc are mounted on a patient's body by means of adhesive media or spring loaded clips. The sensors then connect to the monitor (logger) by means of leads and cables. The list of sensors above describes a typical setup for sleep disorders investigations; up to 20 different sensors, leads and cables can be attached to the data logger device.

There are several disadvantages in using these types of recording systems including: connecting wires, can be unintentionally pulled by the patient during the night can dislodge sensor(s), which will lead to the loss of data; setup and connection of multiple leads and cables requires an assistance of trained technician; long wires become a source of common mode noise in the sensitive front-end circuits of acquisition system, and; the high cost of this technology due to the number of sensors required.

It would be advantageous to locate biological sensors and data logging device in such a way that the number and length of leads and cables required is minimal.

OBJECT OF THE INVENTION

It is an object of the present invention to provide a diagnostic medical device which monitors physiological parameters during sleep and method of its use which is simple to use, reliable and noise free for prolonged acquisition of multiple biological signals during sleep. At the very least, the object of the invention is to provide an alternative to known monitoring devices.

DISCLOSURE OF THE INVENTION

According to one aspect of the present invention there is disclosed a diagnostic medical device which monitors physiological parameters during sleep, said device including a mask means adapted to fit over the nose and mouth of a patient being monitored, an acquisition unit being adapted to be removeably fitted to the mask means, said mask means having inlet means to allow the patient to breath, wherein said acquisition unit including sensor means which monitor physiological conditions and which provide physiological signals thereto for storage or real time data transmission to external devices.

Preferably, the mask means is a standard nebuliser mask used for oxygen ventilation and respiratory support having ventilation holes for an external air supply.

Preferably, the acquisition unit is attached to the mask by means of anchors protruding through pre-punched holes in the soft plastic of the mask.

Preferably, the inlet means is adapted to be provided for positive pressure oxygen intake, connection of air mass flow measurement devices or air pressure sensors.

Preferably the sensor means are located internally or externally of the body of the acquisition unit. For instance, the acquisition unit has an air inlet which takes airflow from the mask for air flow and air pressure monitoring. Preferably, the outer diameter of the air inlet matches the standard size of an oxygen hose.

A temperature sensor is preferably positioned within the mask and an ear mounted pulse oximeter spring clip assembly is preferably connected to the acquisition unit via short leads. EEG electrodes, ECG and plethysmography leads are also connected to the acquisition unit via short leads. Preferably, a connector is used for recorded data uploading and internal battery re-charging or for a real time data transmission.

The system preferably monitors the following physiological signals:

- air flow
- air pressure
- air temperature
- ECG signal
- EEG signal
- plethysmography signal for chest movement monitoring
- oximetry.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be now be described with reference to the accompanying drawings in which:

Fig. 1 is a schematic side view of a patient wearing a standard disposable nebuliser type mask;

Fig. 2 is a schematic side and front view of the patient and mask of Fig. 1 with an acquisition unit attached to the mask;

Fig. 3 is a schematic side and front view of the acquisition unit shown in Fig. 2 with sensor attachments thereto;

Fig. 4 is a schematic front view of the patient wearing the mask having the sensor attachments being attached between the acquisition unit and the relevant parts of the patient's body;

Fig. 5 is a bottom view of the nebuliser mask of Fig. 1; and

Fig. 6 is detailed view of the anchoring of the acquisition unit to the nebuliser mask.

BEST MODE OF CARRYING OUT THE INVENTION

In the preferred embodiment a system for sleep investigation is described. The system preferably monitors the following physiological signals:

- air flow
- air pressure
- air temperature
- ECG signal
- EEG signal
- plethysmography signal for chest movement monitoring
- oximetry.

A standard disposable nebuliser type mask is used in the preferred embodiment of the invention, however, other types of masks are also within the scope of the invention. The standard masks are used for life supporting oxygen ventilation and respiratory support. The mask of the preferred embodiment as seen in Fig. 1 where a person 1 wears a disposable nebuliser type mask 2 having ventilation holes 3 on either side of the mask 2, the holes 3 providing for external fresh air. A standard size inlet 4 is used for positive pressure oxygen intake, connection of air mass flow measurement devices or air pressure sensors as will be described.

As seen in Fig. 2, an acquisition unit 5 is preferably attached to the mask 2 by means of two anchors 6, protruding through pre-punched holes in the soft plastic of the mask 2. This anchoring effectively locks into position the acquisition unit 5.

Referring to Fig. 3 where two views of the acquisition unit 5 are shown, an air inlet 7 of the acquisition unit 5 takes airflow from the mask 2 for air flow and air pressure monitoring. The outer diameter of inlet 7 matches the standard size of an oxygen hose (not illustrated). A temperature sensor 8 which is preferably

positioned within the mask 2 partially protrudes into the mask via a pre-punched hole in the front surface of the mask 2. An ear mounted pulse oximeter spring clip assembly 10 is connected to the acquisition unit 5 via a short cable 9. EEG electrodes 11 are also connected to the acquisition unit 5 via short leads 12. Furthermore, ECG and plethysmography leads 13 are connected to the acquisition unit 5 via short leads 14 and a connector 15 is used for recorded data uploading and internal battery re-charging or for a real time data transmission. A LED 16 indicates progress of any data logging.

In use as seen in Fig. 4, the person 1 wears mask 2 with an acquisition unit 5 attached. Pulse oximetry is monitored via the oximeter 17, air flow and air pressure are monitored via the air inlet 18 of the mask 2, EEG signals are acquired via the EEG leads 19, air temperature is monitored via a thermistor 20 and ECG/plethysmography signals are monitored via leads 21.

The preferred embodiment of the invention as seen from Fig. 4, shows the cables attached to the head sensors are short and arranged for minimal impact from patient's movements in sleep. Leads for ECG/plethysmography signals are much shorter than leads used in standard sleep studies. Clearly since all the elements of the system are attached to the body, arrangement of sensors and setup of the system can be performed by the person with the assistance of a mirror.

The acquisition system and the body of the person form a closed, self-contained structure less susceptible to common mode electrical noise and sensor displacement due to any movements. If real time acquisition is conducted, only a single external connection using a light cable is required.

The disposable nebuliser type mask 2 with two pre-punched anchoring holes 22 and thermistor hole 23 is shown in Fig. 5. The position of the punched holes is defined by the shape of acquisition unit 5.

Referring to Fig. 6, a detailed view of the anchoring is shown. The position of acquisition unit 5 is located by the anchors 6 which protrude through the pre-punched anchoring holes 26 in the soft plastic of the mask 25. The shape of

the anchors 6 allows for a low-force attachment to the mask. By pulling the acquisition unit 5 with sufficient force, it can be separated from the mask for replacement and data transfer.

The foregoing describes only one embodiment of the present invention, and modifications obvious to those skilled in the art can be made thereto without departing from the scope of the present invention.

CLAIMS

1. A diagnostic medical device which monitors physiological parameters during sleep, said device including mask means adapted to fit over the nose and mouth of a patient being monitored, and an acquisition unit being adapted to be removeably fitted to the mask means, said mask means having inlet means to allow the patient to breath, and wherein said acquisition unit includes sensor means which monitor physiological conditions and which provide physiological signals thereto for storage or real time data transmission to external devices.
2. A diagnostic medical device according to claim 1, wherein the mask means is a standard nebuliser mask used for oxygen ventilation and respiratory support having ventilation holes for an external air supply.
3. A diagnostic medical device according to either claim 1 or claim 2, wherein the mask is made from soft plastic and the acquisition unit is attached to the mask by means of anchors protruding through pre-punched holes in the soft plastic of the mask.
4. A diagnostic medical device according to any one of the preceding claims, wherein the inlet means is adapted to be provided for positive pressure oxygen intake, connection of air mass flow measurement devices or air pressure sensors.
5. A diagnostic medical device according to any one of the preceding claims, wherein the sensor means are located internally of the body of the acquisition unit.
6. A diagnostic medical device according to any one of claims 1 to 5, wherein the sensor means are located externally of the body of the acquisition unit.
7. A diagnostic medical device according to any one of the preceding claims, wherein a temperature sensor is positioned within the mask and an ear mounted pulse oximeter spring clip assembly is connected to the acquisition unit via short

leads, and wherein EEG electrodes and ECG and plethysmography leads are also connected to the acquisition unit via short leads.

8. A diagnostic medical device according to any one of the preceding claims, wherein a connector is used for recorded data uploading and internal battery re-charging or for a real time data transmission.

9. A diagnostic medical device according to any one of the preceding claims, wherein the device monitors any one or more of the following physiological signals: air flow, air pressure, air temperature, ECG signal, EEG signal, plethysmography signal for chest movement monitoring, or oximetry.

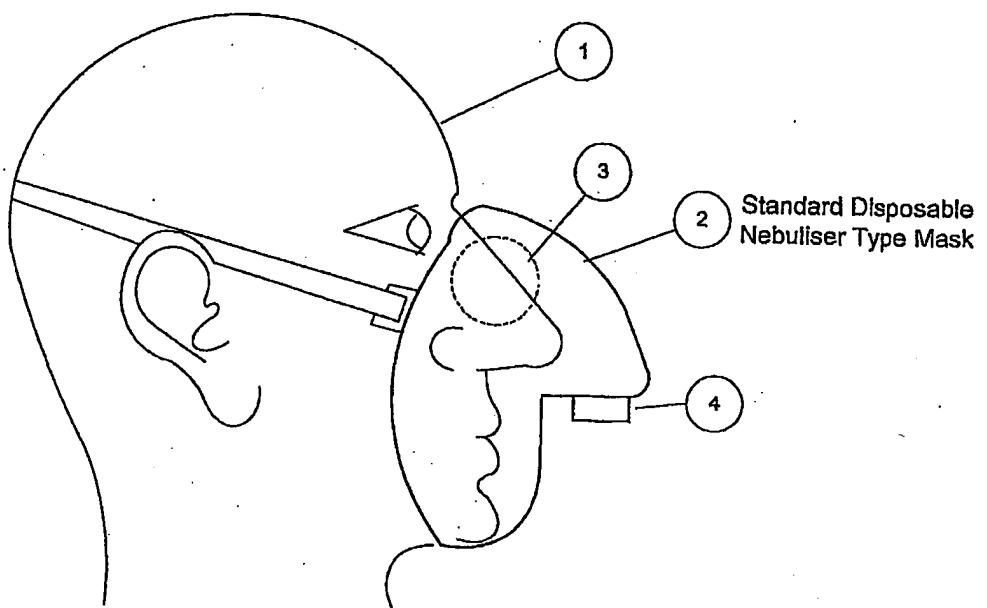


FIG.1

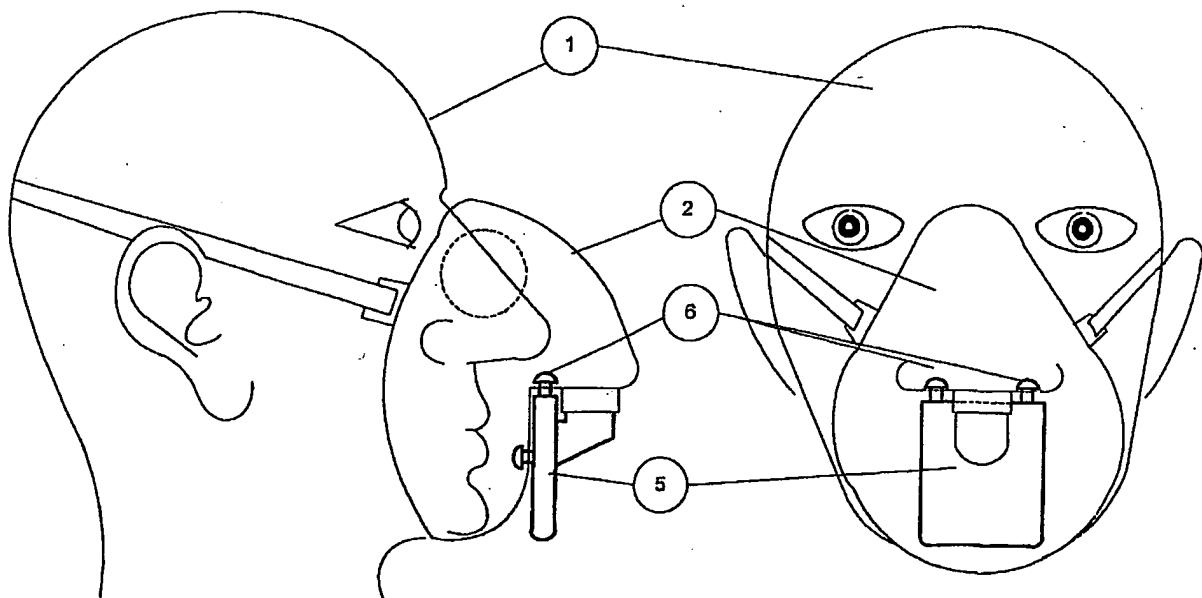


FIG.2

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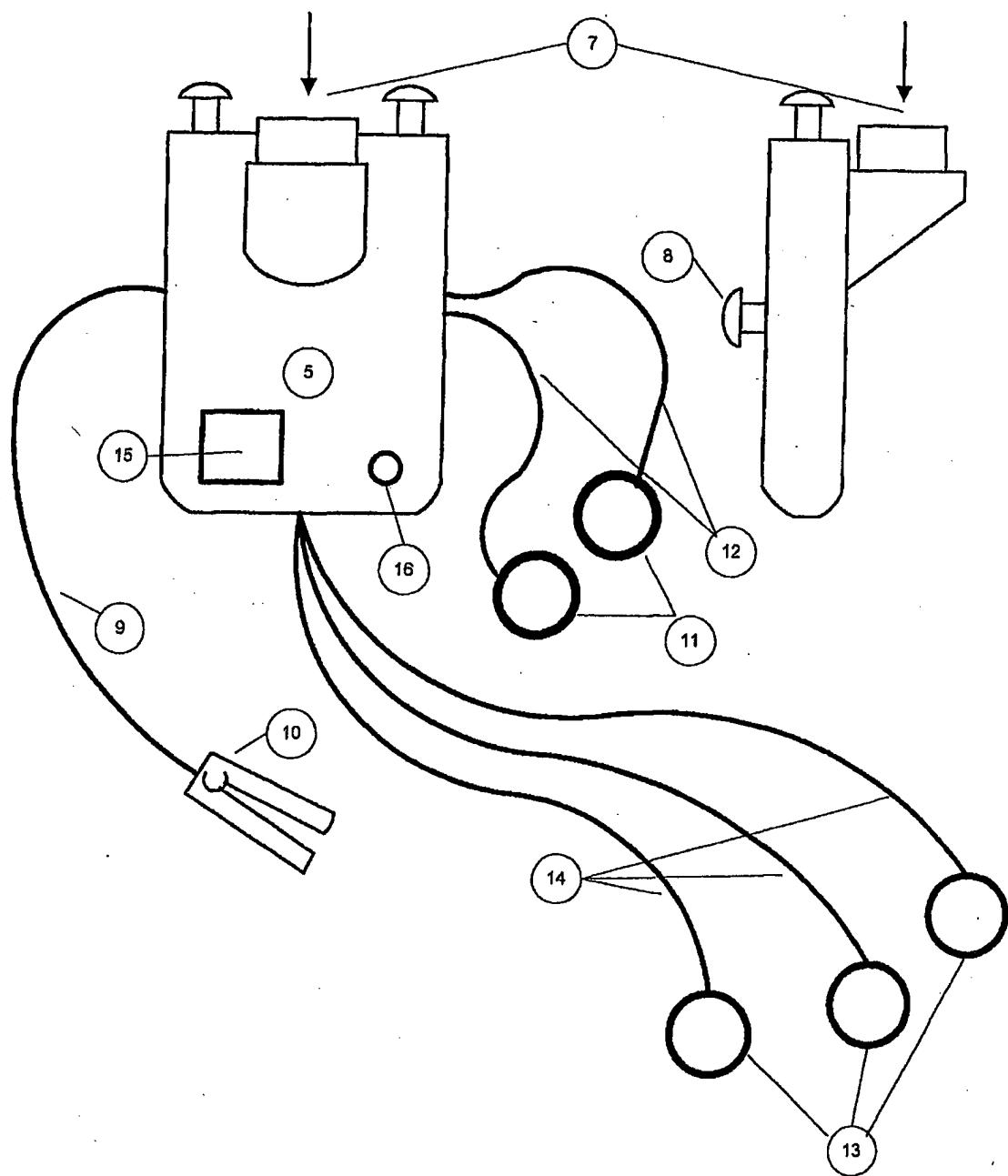


FIG. 3

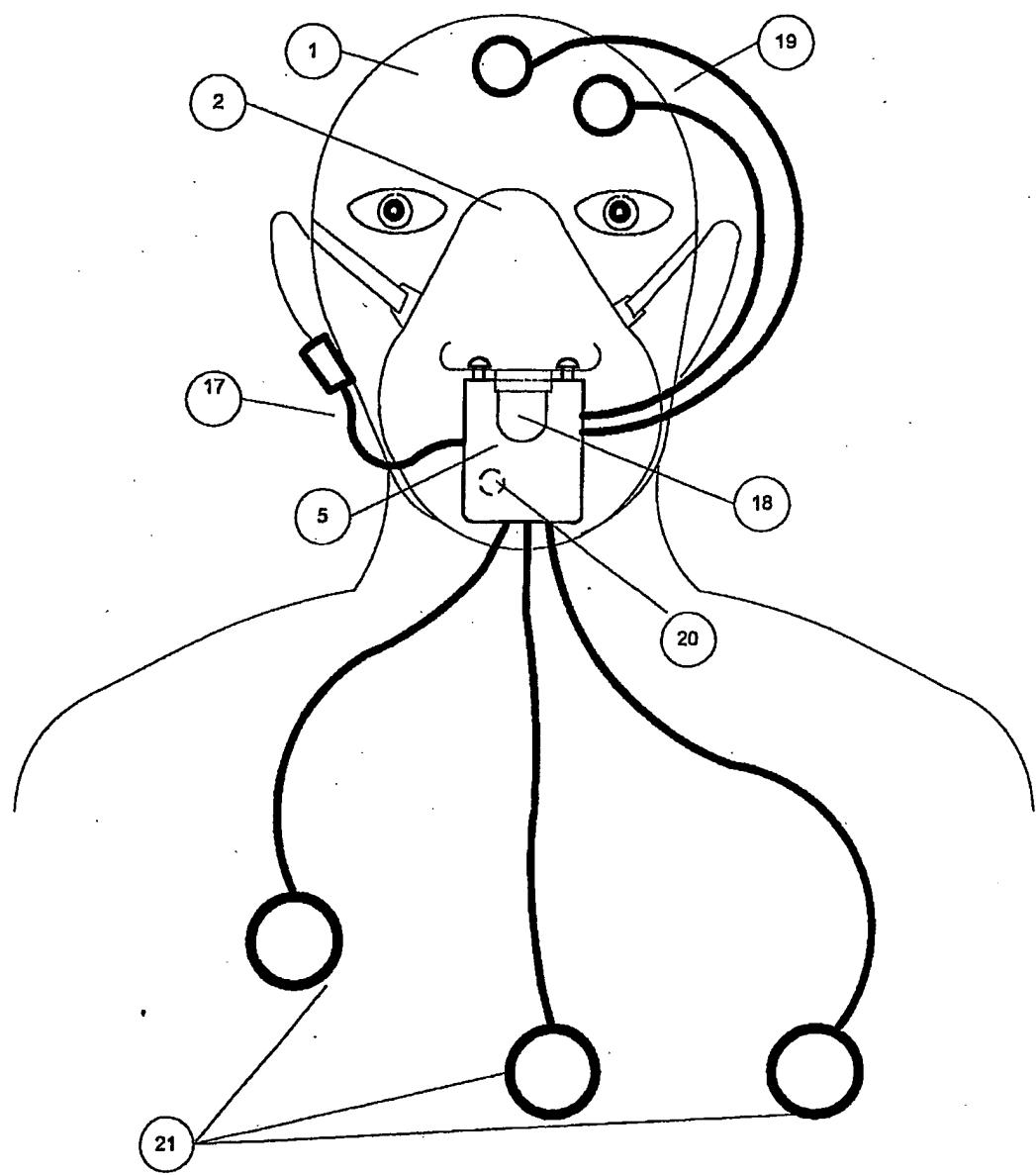


FIG. 4

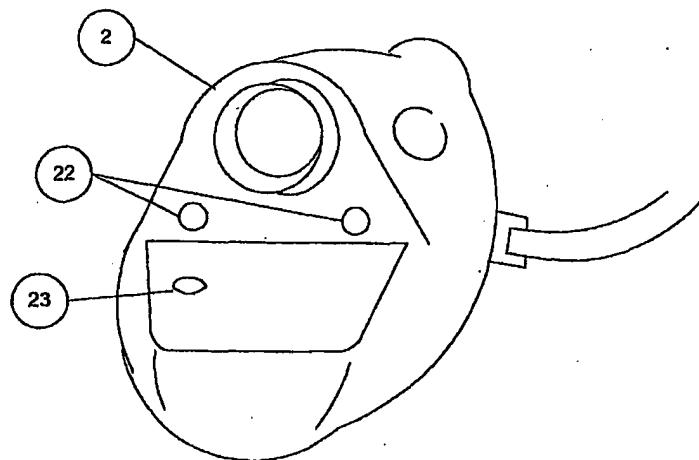


FIG.5

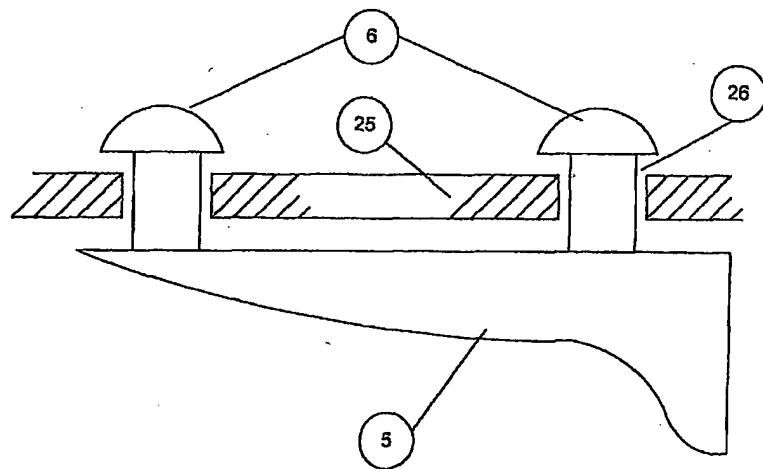


FIG.6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/01055

A. CLASSIFICATION OF SUBJECT MATTER																						
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According to International Patent Classification (IPC) or to both national classification and IPC																						
B. FIELDS SEARCHED																						
Minimum documentation searched (classification system followed by classification symbols) REFER ELECTRONIC DATA BASE CONSULTED BELOW																						
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched																						
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI: & keywords: A61M16/-, A62B/-, A61B/-, mask, diagnos, monitor, analy, measur, sens, acquisit, record, stor, collect, unit, device, box, removabl, detach, demount, portable, stor, transmit, remote,etc.																						
C. DOCUMENTS CONSIDERED TO BE RELEVANT																						
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																				
X	DE 3724336 A (DRAGERWERK AG) 2 February 1989 See figure.	1,4,5,8,9																				
X	US 1039 H (TRIPP, JR et al) 7 April 1992 See figures.	1,4,5,8,9																				
P,X	US 6199550 B1 (WIESMANN et al) 13 March 2001 See figures.	1,4,5,8,9																				
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex																						
<p>* Special categories of cited documents:</p> <table> <tr> <td>"A"</td> <td>document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T"</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E"</td> <td>earlier application or patent but published on or after the international filing date</td> <td>"X"</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L"</td> <td>document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y"</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O"</td> <td>document referring to an oral disclosure, use, exhibition or other means</td> <td>"&"</td> <td>document member of the same patent family</td> </tr> <tr> <td>"P"</td> <td>document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table>			"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E"	earlier application or patent but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family	"P"	document published prior to the international filing date but later than the priority date claimed		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention																			
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Date of the actual completion of the international search 12 November 2001	Date of mailing of the international search report 22 NOV 2001																					
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer SUE THOMAS Telephone No : (02) 6283																					

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/01055

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 01/43804 A1 (COMPUMEDICS SLEEP PTY LTD) 21 June 2001 See figures.	1,4,5,8,9
P,A	DE 19953866 A1 (CORTEX BIOPHYSIK GmbH) 13 June 2001 See figures.	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU01/01055

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report			Patent Family Member		
DE	3724336	EP	303056	JP	1049535
US	H1039				US 4875477
US	6199550				
WO	01/43804				
DE	19953866	WO	2001134022		
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